

**[Cantor Colburn Client Alert:](#)**  
**USPTO Examination Guidance Memo Addresses  
Subject Matter Eligibility of Method of Treatment Claims**

**Summary**

[In a memorandum dated June 7, 2018](#), the USPTO set out new examination guidance concerning method-of-treatment claims, which is encouraging news for patent applicants in the personalized medicine space. The memo emphasizes that method of treatment claims can be found to satisfy subject matter eligibility under 35 USC § 101 at the first step of an Alice/Mayo analysis, without requiring a showing of “nonroutine or unconventional steps.” The memo provides helpful guidance to examiners and patent applicants that emphasizes the patent eligibility of personalized method of treatment claims.

**Client Alert**

On June 7, 2018, the USPTO issued a memorandum providing patent eligibility examination guidance based on the recent Federal Circuit decision in *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals* (887 F.3d 1117 (Fed. Cir 2018)). The so-called “Vanda memo” emphasizes that method of treatment claims can be found to satisfy subject matter eligibility under 35 USC § 101 at the first step of an Alice/Mayo analysis, i.e., whether the claims are directed to a judicial exception such as a natural law or natural relationship, without requiring a showing of “nonroutine or unconventional steps” in the use of the natural law or relationship, provided that the claims, when read in their entirety, are directed to applications of the natural laws or relationships and not the laws or relationships themselves.

In *Vanda*, the claims at issue were directed to methods of treating a patient suffering from schizophrenia using a specific set of analytic steps and administering iloperidone in specific dosage ranges. The PTO memo emphasizes that the Federal Circuit found the claims at issue to be patent eligible because they were not directed to a judicial exception, and that the patentee was not trying to impermissibly claim exclusive rights to the natural law. The memo cites the court’s explanation that while the invention may have stemmed from recognition of naturally-occurring “relationships between iloperidone, CYP2D6 metabolism, and QTc prolongation,” the inventors did not claim the relationships per se, but rather claimed “an application of that relationship.” The memo states that the court held the claims “patent eligible because the claims were directed to a specific method of using iloperidone to treat schizophrenia,” rather than being directed generally to the natural relationship itself. This guidance is in keeping with other court decisions in finding subject matter eligibility in specific applications of natural laws. See, *Rapid Litigation v. CellzDirect*, 827 F.3d 1042 (Fed. Cir. 2016) (methods of cryopreserving cells using a specific protocol of freeze and thaw steps patent eligible) and *Diamond v. Diehr*, 450 US 175 (US Supreme Court, 1980) (method of curing rubber using the Arrhenius Equation found patent eligible).

The Vanda memo provides helpful guidance to examiners and patent applicants that emphasizes the patent eligibility of personalized method of treatment claims. In particular, if method of treatment claims utilize a natural law or relationship as a feature, additional features, steps, or limitations should be included in those claims so that they can be considered applications of the natural laws. Such limitations may include features such as specific timing of drug administration, specific dosages, or assays of specific metabolites.

Although the memo states that existing USPTO patent eligibility guidance already supports finding method of treatment claims eligible, examiners have rejected such claims based on Mayo and asserted that the claims at issue were method of treatment claims in view of the “administering” step. The Vanda memo now makes it clear Patent Office examination policy that can be asserted by patent applicants to reduce the instances of such rejections and provide a path forward for arguing subject matter eligibility of personalized method of treatment claims.

#### **For Further Information and Assistance**

Please do not hesitate to contact your [Cantor Colburn attorney](#) with any questions you may have regarding this matter and your IP in general.

Partner [Todd E. Garabedian, Ph.D.](#) is available for further questions at [tgarabedian@cantorcolburn.com](mailto:tgarabedian@cantorcolburn.com).

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